

Sample Prep for Quality Control

Quality control (QC) is a critical step in the biopharmaceutical and medical device industry.

Each manufacturer must demonstrate that its drugs and devices are consistently produced, safe, potent, and pure. The number of tests that must be run by QC labs continues to rise to meet the ever increasing QC requirements of global regulatory agencies.

Sartorius offers analytical sample preparation solutions to support ultra-trace level of detection in high pressure liquid chromatography (HPLC), liquid chromatography, mass spectrometry, ion chromatography (LC-MS, IC), or inductively coupled plasma mass spectrometry (ICP-MS) filtration solutions.



1 Preparation of Solvents

Tests have proven that up to 80% of the problems occurring during HPLC runs are attributable to inadequate water quality.

Highly pure mobile phases are crucial for top analytical-grade quality, requiring eluents free from organic impurities or particles. Often, even purchased HPLC-grade water has high total organic carbon (TOC) levels. Compact Arium® Mini laboratory water systems, designed for Type 1 ultrapure water needs of 10 liters per day, are perfect for preparing buffers, media, and samples in life sciences and analytical laboratory procedures.

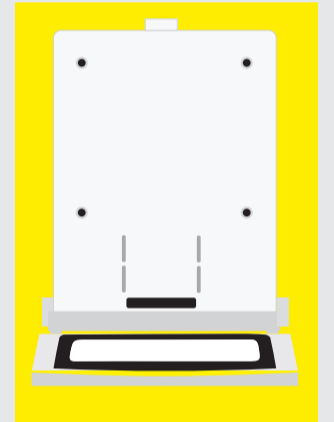


2 Preparation of Standards

Cubis® II is engineered in accordance with US FDA data integrity principles, ensuring data is:

- Accurate
- Legible
- Contemporaneous
- Original
- Attributable

The Cubis® II balance, equipped with a pharma package, incorporates all necessary technical controls for full regulatory compliance. The YAPP16 software application manages the dosing system, featuring a database for solvents, components, and samples. It guides users through the entire process of preparing single or mixed standards with specified concentrations.



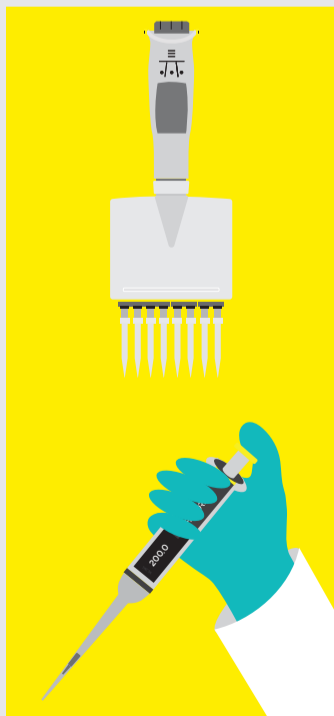
3 Liquid Handling

To ensure safe and reliable transfer of even the smallest volumes, pipetting accuracy is essential.

Picus® 2 electronic pipettes offer repeatable pipetting results and step-by-step guidance for your various pipetting protocols.

Tacta® mechanical pipettes are perfectly balanced to meet all your needs during pipetting. Their ergonomic design and low weight ensure easy and convenient handling.

Pipette and tip act as a system. The best fitting pipette tips for Sartorius pipettes are Optifit standard and Safetyspace® Filter Tips. They ensure the accurate performance of Sartorius pipettes and repeatability of your results.



4 Filtration

Filtration to remove particles from samples directly impacts the separation efficiency of the HPLC column and thus the reliability of the results.

The Claristep® filtration system confers total ease of use. The patented design of the Claristep® station allows a user to filter up to eight 60 µL to 600 µL HPLC samples in parallel, without the need for AC power, vacuum pumps or syringes.

Minisart® PP syringe filters optimized for sample preparation consist of a polypropylene housing and membrane components featuring maximum chemical compatibility and minimum extractables to ensure excellent results.

